

*NO
C-1*
(Amendment
U.S. Appln. No. 09/381,561)

2426-1-001

reagents and protective packaging for transport of the recording device to a processing facility.

REMARKS

Applicant respectfully requests reconsideration of the grounds of rejection stated in the Office Action and allowance of all pending claims for the reasons set forth herein below.

SUMMARY OF THE REJECTIONS

I. Claims 20-39 stand rejected under 35 U.S.C. §112, first paragraph.

II. Claims 39 stands rejected under 35 U.S.C. §112, second paragraph.

III. Claims 20-39 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Chow (U.S. 5,955,028).

IV. Claims 20-39 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over the combination of Hillman et al. (U.S. 4,756,884 and 4,,963,498 hereafter "Hillman'884" and "Hillman'498" respectively) in view of either Galen at al. (U.S. 5,695,949 hereafter "Galen") or Phillips et al. (U.S. 5,179,005 and 5,426,032 hereafter "Phillips '005" and "Phillips'032" respectively).

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APPLICANT'S TRAVERSAL

I. Claims 20-39 stand rejected under 35 U.S.C. §112, first paragraph because it is alleged in the Office Action that the limitation "wherein said recording part only records the said assay information without analyzation thereof in a form suitable for onward transmission for subsequent processing and analysis at a remote data processing site" is allegedly new matter.

Applicant respectfully but strongly disagrees with the above characterization in the Office Action that the amendment to Claim 20 constitutes new matter, because the recording part is just that, a recording part for the recording of raw data from the reagent impregnated filter paper (or other suitable means, please see page 9, lines 25 to page 10, line 9 regarding the primary assay reagent conduit), which is in fluid connection with the sample well.

As stated on page 13 of the specification, the user simply detaches the recording part from the assay part and sends the recording part containing the raw data to a processing facility for decoding and interrogation. Alternatively, the raw data can be sent via the Internet or other telecommunication means.

Moreover, Applicant respectfully submits that the specification states at page 2, line 26 to page 3, line 7:

In addition, it may be desirable to analyze the recorded result of an assay by a healthcare worker

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at a data processing site remote from the patient
than rely on the patient to record and report the result of the test. There are certain patients (i.e. those suffering from mental disorders, e.g. depression, schizophrenia), where it may be desirable to keep the results of an assay secret until the healthcare worker can process the data to enable the correct diagnosis to be determined. It is well known in the art that patients can willfully interfere with an assay to give an erroneous measure of the particular variable monitored by the assay. If the recording device merely records the information for subsequent processing and analysis this possibility is minimized. (Emphasis by underlining and italics added).

Thus, it is respectfully submitted that the above passage of the instant specification clearly enables the clarification made to claim 20 in the previously-filed amendment, and does not constitute the addition of new matter. Reconsideration and withdrawal of this ground of rejection are respectfully requested.

II. Claim 39 has been amended to overcome the rejection under 35 U.S.C. §112, second paragraph by now reciting a "kit comprising an assessment device according to any of claims 20-37..." so as not to depend upon method claim 38. Reconsideration and withdrawal of this ground of rejection are respectfully requested.

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III. Claims 20-39 stand rejected as allegedly anticipated under 35 U.S.C. §102(e) as allegedly anticipated by Chow. Applicant respectfully traverses this ground of rejection for the reasons herein below.

Chow merely discloses an analytical system comprising a base unit, an adapter and a substrate. The adapter permits different substrates to be placed in the analytical system, and this reference envisions performing the entire analysis locally in a conventional manner. For example, Chow discloses a need for providing potentially complex data collection and analysis locally, along with the assay equipment at the site where the assay is performed.

In contrast, in the presently claimed invention, the assay part performs the assay procedure on a sample, and is recorded by a recording part. The recording part is detachable from the assay part so that the data may be onwardly transmitted for subsequent processing and analysis at a remote data processing site. Claim 21 further recites that the device is sized for personal handling by a user or technician to facilitate transport to a processing facility by a common courier.

In other words, the user places a sample in the sample well 13 (please see, for example. Figs. 2a and 2b), and after an indication

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that the sample has been recorded by indicator 9, the detachable recording part 10 can be detached and sent separately to a processing facility.

The above system provides an inexpensive device that can be used remotely by a patient or technician, and prevent the tampering of the item being monitored by the assay because the processing and analysis is performed remotely. The claimed invention also is distinguishable from other home test devices, which provide processing and analysis locally.

For all the foregoing reasons, it is respectfully submitted that none of the present claims are anticipated by Chow because the reference fails to disclose or suggest all of the elements recited in the present claims. Reconsideration and withdrawal of this ground of rejection are respectfully requested.

IV. Applicant respectfully submits that the rejection of claims 20-39 under 35 U.S.C. §103(a) over the combination of Hillman'884 and Hillman'498 in view of either Galen, or Phillips'005 and Phillips'032 is traversed.

The Office Action admits that Hillman fails to disclose a detachable recording part. However, neither do Galen or the Phillips references disclose a detachable recording part.

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Accordingly, the combination of references fails to disclose all of the elements recited in Applicant's claims.

Moreover, although the Office Action alleges that the microprocessor in the Galen and the Phillips references are a recording part, none of these references disclose a detachable recording part that is attached to an assay part to collect data, and subsequently detached for subsequent processing and analysis, as presently claimed.

Applicant also respectfully submits that this ground of rejection is improper because it is confusing the detachable recording part of the present invention with the use of a microprocessor as taught by Galen or Phillips. The presently claimed invention does not require a microprocessor as a recording device. The detachable recording part can be, for example, photographic (please see the specification at page 5, lines 2-4).

In fact, as disclosed at page 11, lines 14-18 of the specification, the recording part can be, *inter alia*, (1) sensitive film or device recording a photometric reaction by a photographic or other sensitive light, (2) reflectance or transmittance photometry, or production of a stable dye on a surface by biochemical or chemical reaction, (3) microparticles, including polymers, metallic and non-metallic elements and other materials,

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(4) soluble colored substances, including dyes, which can be determined by light reflectance techniques, such as fluorimetry, or techniques related to any specific feature of any soluble substance used, and (5) other assay detection systems.

Therefore, it is respectfully submitted that the present claims would not have been obvious to a person of ordinary skill in the art over the combination of the cited references, because the combination fails to disclose or suggest to an artisan all of the features recited by the present claims.

Reconsideration and withdrawal of this ground of rejection are respectfully requested.

In light of the foregoing, it is respectfully submitted that the present application is in condition for allowance, and a notice to that effect is respectfully solicited.

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If any issues remain which may best be resolved through a telephone communication, the Examiner is requested to kindly telephone the undersigned at the telephone number listed below.

Respectfully submitted,



Stephen Gigante
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Registration No. 42, 576

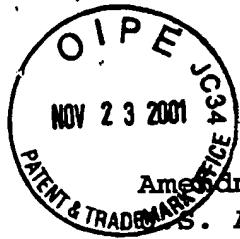
Date: November 21, 2001

SG/lc

Enclosure - Version with Markings To Show Changes Made
Three-Month Extension of Time

Attorney Docket No. 2426-1-001

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S. Appln. No. 09/381,561

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Inventors: James Richard Jackson Art Unit: 1641

Serial No.: 09/381,561 Examiner: M. Pham

Filed: September 17, 1999

For: RECORDING ASSAY DEVICE

VERSION WITH MARKINGS TO SHOW CHANGES MADE

U.S. Patent and Trademark Office
P.O. Box 2327
Arlington, VA 22202

Dear Sir:

In response to the Office Action dated May 22, 2001, the Applicant hereby petitions for a three-month extension of time and requests amendment of the above-identified application as follows:

IN THE CLAIMS:

39. (Amended) A kit comprising an assessment device according to any [preceding claim] of claims 20-37 comprising an assessment device, assay reagents and protective packaging for transport of the recording device to a processing facility.